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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,570	09/11/2007	**Shinichi Watanabe**	11582-016-999	5811

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EXAMINER	
TON, THAIAN N	
ART UNIT	**PAPER NUMBER**
1632	
MAIL DATE	**DELIVERY MODE**
07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,570	WATANABE ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) *15,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8,10-14,16,19-23,25 and 26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Preliminary amendment, filed 12/20/05, has been entered. Claims 9 and 24 are cancelled; claims 1-8, 10-23, 25-26 are pending.

Claim 15 is withdrawn because it is an improper multiple dependent claim. The claims read that the reagent is identified by the method of "any of claim 10-12". Thus, this claim does not recite the claims in the alternative, and is thus, an improper multiple dependent claims.

Claims 17-18 are withdrawn. These claims are drawn to "use of" a pharmaceutical composition. These claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

If Applicants amend these claims, the Examiner will determine, at that time, if the amended claims are representative of the elected group.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1+, claim(s) 1-3 and 5, drawn to an isolated polynucleotide encoding a RC kinase polypeptide, vectors, host cells, and a method for producing a RC kinase polypeptide.

Group 2+, claim(s) 4, drawn to a substantially purified RC Kinase polypeptide.

Group 3+, claim(s) 6-7, drawn to a method for detection of a polynucleotide encoding an RC kinase polypeptide by hybridizing a polynucleotide to a nucleic acid material, thereby forming a hybridization complex; and detecting said hybridization complex.

Group 4+, claim(s) 8, drawn to a method for detection of a polynucleotide by contacting a biological sample with a reagent that specifically interacts with the RC kinase polynucleotide.

Group 5+, claim(s) 8, drawn to a method for detection of a polypeptide by contacting a biological sample with a reagent that specifically interacts with the RC kinase polypeptide.

Group 6+, claim(s) 10, drawn to a method for screening agents which decrease the activity of a RC kinase by contacting a test compound with an RC polypeptide and detecting binding to the polypeptide.

Group 7+, claim(s) 11-12, 14, drawn to a method for screening agents which regulate the RC kinase activity by contacting a test compound with a RC kinase polypeptide, a method of reducing RC kinase activity by contacting a cell with a reagent that specifically binds to an RC kinase polypeptide.

Group 8+, claim(s) 13, drawn to a method for screening for agents which decrease the activity of a RC kinase by contacting a test compound with an RC kinase polynucleotide.

Group 9+, claim(s) 19-22, 25(a) drawn to methods for the prediction, diagnosis or prognosis of respiratory diseases by detection of expression level of the RC kinase gene, methods of prediction, diagnosis or prognosis of COPD by detection of at least one marker; a composition comprising the detection agent.

Group 10+, claim(s) 23, 25(b) drawn to methods for the prediction, diagnosis or prognosis of COPD by detection of at least 2 markers, and the detection agent.

Group 11+, claim(s) 26, drawn to an array comprising a plurality of polynucleotides.

The inventions listed as Groups 1^{+}-11^{+} do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product

2) A product and a process of use of said product
3) A product, a special process of manufacture of said product, and a process of use of said product
4) A process and an apparatus specially designed to carry out said process
5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:
"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:
"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) states:
"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

In the instant case, Unity of Invention is lacking in the instant claims because the allowed combinations do not allow multiple products, multiple methods of make and/or using the products. Each of the sequences that are claimed in claim 1 represent a distinct product. Accordingly, the Groups are not so linked by the same or corresponding technical feature to form a single, general inventive concept.

Sequence Election Requirement

Additionally, upon election of a specific group, Applicants are required to elect a single sequence for examination. It is noted that this is not a species

requirement, but a Group requirement, as noted above, because each sequence constitutes a separate product.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, the Commissioner has stated that, "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371." See Examination of Patent Applications Containing Nucleotide Sequences 1316 OG 122 (March 27, 2007). **For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.**

If Applicants elect Group 10+, Applicants are request to elect two sequences for examination.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinde**r. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632